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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/636,826 | 08/14/2000 | Eike Duweing | 50615 | 8623 |

26474 7590 10/22/2002

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EXAMINER

COLLINS, CYNTHIA E

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| ART UNIT | PAPER NUMBER |
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1638

DATE MAILED: 10/22/2002 11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/636,826

Applicant(s)

DUWEING ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 13 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 55-99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 55-99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

The Amendment filed August 13, 2002, paper no.10, has been entered.

Claims 1-54 are cancelled.

Claims 55-99 are newly added. Applicant should note that because the newly added claims 55-100 did not include a claim number 63, newly added claims 64-100 have been renumbered as claims 63-99 pursuant to rule 1.126.

Claims 55-99 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 55-61, 63-93 and 95-99 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record pertaining to claims 1, 3-5, 7, 9-10, 13-23 and 51-54 set forth in the office action mailed April 23, 2002.

Applicant's arguments filed August 13, 2002, have been fully considered but they are not persuasive.

Applicant argues that because the Examiner stated that the specification is enabling for the elected promoter of the *B. vulgaris* plant V-ATPase subunit c isoform 2 set forth in SEQ ID

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NO:1, and because the newly submitted claims are only directed to a promoter of the plant V-ATPase subunit c isoform 2, the rejection has been overcome (reply page 13).

Limitation of the newly submitted claims to a promoter of the plant V-ATPase subunit c isoform 2 does not overcome the written description rejection, as Applicant has not described a representative number of plant V-ATPase subunit c isoform 2 promoters. Applicant has described a single plant V-ATPase subunit c isoform 2 promoter, the elected promoter of the *B. vulgaris* V-ATPase subunit c isoform 2 set forth in SEQ ID NO:1. The disclosure of a single plant V-ATPase subunit c isoform 2 promoter from one plant species does not provide an adequate description of the claimed genus, and in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus that comprises plant V-ATPase subunit c isoform 2 promoters. Limitation of the newly submitted claims to a promoter of the plant V-ATPase subunit c isoform 2 also does not overcome the scope of enablement rejection, as Applicant has disclosed only one nucleotide sequence obtained from a plant V-ATPase subunit c isoform 2 gene that has promoter function, the elected sequence of the *B. vulgaris* V-ATPase subunit c isoform 2 set forth in SEQ ID NO:1.

Claims 55-99 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA constructs comprising the elected promoter of the *B. vulgaris* V-ATPase subunit c isoform 2 set forth in SEQ ID NO:1, expressing a heterologous gene, and producing a recombinant protein, does not reasonably provide enablement for DNA constructs comprising plant V-ATPase promoters, or plants, plant cells or protoplasts which are resistant to

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biotic or abiotic stress, or salt stress, for the reasons of record pertaining to claims 1, 3-7, 9-11, 13-41, 43-44, 49 and 51-54 set forth in the office action mailed April 23, 2002. The rejection under 35 U.S.C. 112, first paragraph, for scope of enablement was not specifically addressed in the reply filed August 13, 2002.

Claims 55 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "functional equivalent", for the reasons of record pertaining to claims 1 and 11 set forth in the office action mailed April 23, 2002.

Applicant's arguments filed August 13, 2002, have been fully considered but they are not persuasive.

Applicant argues that the term "functional equivalents is defined in the specification at page 14 as including all DNA sequences which are complementary to a DNA sequence, which hybridize with a reference sequence under stringent conditions, and which show an activity which is similar to that of a plant V-ATPase promoter (reply pages 14 and 16).

The Office maintains that the definition in the specification does not clarify whether "functional equivalent" in claim 55 refers to the promoter or to a DNA construct. Furthermore, if "functional equivalent" refers to the promoter, the definition in the specification also does not clarify what level of promoter activity would be functionally equivalent.

Claims 55, 61 and 74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "gene", for the reasons of record pertaining to claims 1, 10, 24, 28, 43 and 44 set forth in the office action mailed April 23, 2002.

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Applicant's arguments filed August 13, 2002, have been fully considered but they are not persuasive.

Applicant argues that the term "gene" is defined in the specification at page 14 as isolated DNA sequences which encode peptides or proteins which are other than plant V-ATPase subunits A, c1 or c2. (reply page 14).

The Office maintains that definition of "gene" in the specification at page 14 does not limit the claims, as one skilled in the art would interpret "gene" according to its usual and customary meaning. Applicant's definition does not exclude promoter sequences, noncoding sequences and termination sequences.

Claim 59 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "different manner", for the reasons of record pertaining to claim 7 set forth in the office action mailed April 23, 2002.

Applicant's arguments filed August 13, 2002, have been fully considered but they are not persuasive.

Applicant argues that whichever manner the first promoter is regulated, the second promoter should be regulated in a different manner, and the manner of the first promoter need not be defined (reply page 15).

The Office maintains that claim 59 is indefinite as the manner in which the first and second promoters are regulated cannot be discerned from the claim.

Claim 61 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the manner of recitation of specific heterologous genes, in the recitation of "a resistance-mediating gene", and in the recitation of "other medicinal, agronomical or other interest", for the reasons of record pertaining to claim 10 set forth in the office action mailed April 23, 2002.

Applicant's arguments filed August 13, 2002, have been fully considered but they are not persuasive.

Applicant argues that the term "a resistance-mediating gene" is understood by one of ordinary skill in the art. Applicant also argues that the claim recites "other medicinal, agronomical or other interest" because the selection marker and the resistance mediating gene do not fall within one of these categories (reply page 15).

The Office maintains that the term "a resistance-mediating gene" would not be understood by one of ordinary skill in the art, as the claim does not specify what type of resistance is mediated. The Office maintains that "other" implies that the selection marker and the resistance-mediating gene fall within the categories "medicinal, agronomical or other interest". The Office further maintains that the number and nature of the alternatives present in "other medicinal, agronomical or other interest" is unclear.

Claims 74 and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "gene which has been transformed by means of the DNA construct", as it is unclear how a gene would be transformed by a DNA construct, since a DNA construct is a product and not a method or means step.

Claims 96-97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "which is", for the reasons of record pertaining to claims 51-54 set forth in the office action mailed April 23, 2002. This rejection was not specifically addressed in the reply filed August 13, 2002. It remains unclear whether "which is" refers to a plant cell, a protoplast, or both.

Claims 90 and 91 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claims 90 and 91 are missing the essential step of expressing a recombinant protein. In the absence of recombinant protein expression, the methods of claims 90 and 91 will not result in the production of a recombinant protein. Furthermore, the claimed method does not result in the production of a recombinant protein as set forth in the preamble.

Claims 92-95 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claims 92-95 are missing the essential step of expressing a gene. In the absence of gene expression, the methods of claims 92-95 will not result in the expression of a gene. Furthermore, the claimed method does not result in the expression of a gene as set forth in the preamble.

Claim Rejections - 35 USC § 102

Claims 55-56 58-63 65-67 69, 74, 76, 77, 82, 84-85 and 90 are rejected under 35 U.S.C. 102(b) as being anticipated by Struve et al. (The Journal of Biological Chemistry, Vol. 265, No. 14, May 15, 1990, pages 7927-7932), for the reasons of record pertaining to claims 1, 3-7, 9-11, 13-17, 19, 24-26, 32, 34, 40 and 51 set forth in the office action mailed April 23, 2002.

Applicant's arguments filed August 13, 2002, have been fully considered but they are not persuasive.

Applicant argues that Struve et al. do not disclose a V-ATPase subunit c isoform 2 promoter, or upregulation of the expression of a heterologous gene that is under the control of a promoter derived from a gene of the V-ATPase gene family. Applicant further argues that the promoter taught by Struve et al. cannot be considered a functional equivalent because the promoter taught by Struve et al. would not be functionally equivalent as the term is defined at page 14 of the specification (reply pages 18-19).

The Office maintains that the promoter taught by Struve et al. can be considered a functional equivalent of a V-ATPase subunit c isoform 2 promoter, because the promoter function is not specifically limited in the claims, and because the definition at page 14 of the specification does not limit the function of the claimed promoter. The Office further maintains that the claims are not limited to upregulation of the expression of a heterologous gene.

Claim Rejections - 35 USC § 103

Claims 55-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Struve et al. (The Journal of Biological Chemistry, Vol. 265, No. 14, May 15, 1990, pages 7927-7932), for

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the reasons of record pertaining to claims 18, 20-23, 25, 27-31, 33, 35-39, 41, 43-44 and 53 set forth in the office action mailed April 23, 2002.

Applicant's arguments filed August 13, 2002, have been fully considered but they are not persuasive.

Applicant argues that Struve et al. do not disclose a V-ATPase subunit c isoform 2 promoter, or upregulation of the expression of a heterologous gene that is under the control of a promoter derived from a gene of the V-ATPase gene family. Applicant further argues that a DNA construct comprising a promoter of the ATPase subunit isoform 2 is not obvious to a person of ordinary skill in the art, as a promoter of the ATPase subunit isoform 2 is upregulated under salt stress and under abiotic or biotic stress, which Struve et al. do not disclose (reply pages 19-20).

Applicant's arguments are not commensurate in scope with the claims. The Office maintains that while Struve et al. do not disclose a V-ATPase subunit c isoform 2 promoter, Struve et al. disclose a functional equivalent, as discussed *supra*. The Office further maintains that the claims are not limited to upregulation of the expression of a heterologous gene.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
October 19, 2002


PHUONG T. BUI
PRIMARY EXAMINER 10/21/02